Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Embassy Health Care Center
(CCN: 14-5316),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-258

Decision No. CR2464

Date: November 8, 2011

DECISION

Petitioner, Embassy Health Care Center (Petitioner or facility), is a long-term care facility, located in Wilmington, Illinois, that participates in the Medicare program. In December 2010, state surveyors investigated a complaint that a twenty-four-year-old facility resident had died from "combined drug intoxication." Based on the surveyors' findings, the Centers for Medicare and Medicaid Services (CMS) determined that the facility was not in substantial compliance with Medicare requirements and has imposed against the facility a civil money penalty (CMP) of $300 per day. Petitioner appeals, and CMS moves for summary judgment.

For the reasons set forth below, I grant summary judgment. The undisputed facts establish that the facility was not in substantial compliance with Medicare requirements and that the penalty imposed is not unreasonably high.

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act §1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, after receiving a report that a 24-year-old facility resident died of a drug overdose, surveyors from the Illinois Department of Public Health (State Agency) investigated, completing a complaint investigation survey on December 16, 2010. Based on their findings, CMS determined that the facility was not in substantial compliance with: 42 C.F.R. § 483.25 (Tag F309), the "quality-of-care" regulation; and 42 C.F.R. § 483.25(l) (Tag F329), which protects residents from unnecessary drugs. CMS Exs. 1, 2. As authorized by 42 C.F.R. § 498.56, CMS subsequently added an additional citation – 42 C.F.R. § 483.10(b)(11), which requires that the facility consult the resident's physician about any significant changes in condition. CMS Br. at 2. CMS has imposed against the facility a $300 per day CMP for 13 days of substantial noncompliance (December 16-28, 2010), for a total CMP of $3,900. CMS Ex. 2.[1]

Petitioner timely requested a hearing, and CMS now moves for summary judgment.

[1] CMS initially determined that the facility's deficiencies under 42 C.F.R. § 483.25 posed immediate jeopardy to resident health and safety and imposed a $10,000 penalty for one day of immediate jeopardy (December 15). Following an informal dispute resolution (IDR) proceeding, the scope and severity of that deficiency was reduced to level G (isolated instance of substantial noncompliance causing actual harm that is not immediate jeopardy), and the one day $10,000 penalty was rescinded. CMS Ex. 2; CMS Ex. 5 at 14; *see* 42 C.F.R. § 488.331. CMS does not contest the IDR result. *See* Act § 1819(h)(1), (2); 42 C.F.R. § 488.452(a)(2); *Britthaven of Chapel Hill*, DAB No. 2284 at 6-9 (2009).

CMS submitted a motion for summary judgment and memorandum in support (CMS Br.), along with 38 exhibits (CMS Exs. 1-38). Petitioner submitted a memorandum in opposition to summary judgment (P. Br.) and 7 exhibits (P. Exs. 1-7).

II. Issues

I consider whether summary judgment is appropriate.

On the merits, the issues before me are: 1) was the facility in substantial compliance with Medicare program requirements; and 2) if the facility was not in substantial compliance, is the penalty imposed – $300 per day – reasonable?

I also discuss below why I lack the authority to review CMS's scope and severity findings.

III. Discussion

Summary judgment. Summary judgment is appropriate when a case presents no issue of material fact, and its resolution turns on questions of law. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004); *see also Ill. Knights Templar Home*, DAB No. 2274 at 3-4 (2009) (citing *Kingsville Nursing Ctr.*, DAB No. 2234 at 3-4 (2009)). The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Ctr.*,388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); s*ee also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing and Rehab. Ctr.*, DAB No. 1918 (2004).

> To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact . . . .

Ill.Knights Templar, DAB No. 2274 at 4; *Livingston Care Ctr.* DAB No. 1871 at 5 (2003).

In examining the evidence for purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Brightview Care Ctr.*, DAB No. 2132 at 2, 9 (2007); *Livingston Care Ctr.*,

388 F.3d at 172; *Guardian Health Care Ctr.*, DAB No. 1943 at 8 (2004); *but see Cedar Lake Nursing Home*, DAB No. 2344 at 7 (2010); *Brightview*, DAB No. 2132 at 10 (entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). However, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *Cedar Lake*, DAB No. 2344 *at 7; Guardian*, DAB No. 1943 at 11 ("A dispute over the conclusion to be drawn from applying relevant legal criteria to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts.").

Here, Petitioner all but concedes that no material facts are in dispute and, in any event, points to none. *See* P. Br. at 2 (conceding "[m]any of the facts concerning R1's medical condition, vital signs, etc. are undisputed"); P. Br. at 19 (agreeing "many of the most salient facts are not in dispute"). Petitioner argues, however, that the parties' expert witnesses draw "substantially different inferences from those facts, and from such inferences, substantially different conclusions." P.Br. at 2. But, as the discussion below establishes, Petitioner makes inferences that are simply not reasonable and confuses inferences with legal conclusions. Drawing all reasonable inferences in Petitioner's favor, the undisputed facts lead to only one reasonable conclusion – that the facility was not in substantial compliance with program requirements.

Undisputed facts. Resident 1 (R1) was a twenty-four-year-old woman, admitted to the facility on July 22, 2010. She had a long list of diagnoses, including opiod dependence, bipolar disorder, fibromyalgia, asthma, endometriosis, rheumatoid arthritis, and scoliosis. She suffered chronic back pain and had histories of suicidal ideation, cutting herself, and abusing narcotics. CMS Ex. 23 at 237. Her list of medications was formidable and included no fewer than four antipsychotics, three antidepressants, and one narcotic pain reliever:

- Medrol (a corticosteroid, commonly used to treat asthma, allergies, and arthritis), 4 mg., by mouth, every morning;

- Lithium (an antipsychotic mood stabilizer, commonly used to treat manic episodes), 300 mg., by mouth, twice daily;

- Trazodone (an antidepressant), 350 mg., by mouth, daily at bedtime;

- Risperdal (an atypical antipsychotic), 0.5 mg., by mouth, every morning.

- Risperdal, 1 mg, by mouth, daily at bedtime;

- Seroquel (an atypical antipsychotic used to treat schizophrenia and bipolar), 200 mg., by mouth, daily at bedtime;

- Klonopin (Clonazepam) (an anticonvulsant that was apparently prescribed to treat R1's anxiety, s*ee* CMS Ex. 23 at 165), 2 mg., by mouth, four times daily;

- Wellbutrin (an atypical antidepressant), 300 mg., by mouth, every morning;

- Tylenol (Acetaminophen), 650 mg., by mouth, every 4 hours as needed (PRN);

- Bentyl (used to treat bowel problems), 10 mg., by mouth, every 6 hours PRN;

- Zofran (used to treat nausea and vomiting), 4 mg., by mouth, every 6 hours PRN;

- Motrin, 600 mg., by mouth, every 8 hours PRN;

- Soma (a muscle relaxant), 300 mg., by mouth, three time daily PRN;

- Albuterol INH (a bronchodilator), 2 puffs twice daily PRN;

- Imodium (an anti-diarrheal), 2 mg., by mouth, every 4 hours PRN;

- Ativan (a tranquilizer) 1-2 mg., intramuscular, every 4 hours PRN;

- Ativan, 1-2 mg., by mouth, every 4 hours PRN;

- Cogentin (used to treat muscle spasms caused by antipsychotic medications), 1 mg., by mouth, every 4 hours PRN;

- Cogentin, 1 mg., intramuscular, every 4 hours PRN;

- Maalox 30 ml., by mouth, every 6 hours PRN;

- Geodon (an atypical antipsychotic), 20 mg., intramuscular, every 12 hours PRN;

- Robitussin, 10 ml., by mouth, every 6 hours PRN;

- Milk of Magnesia, 10 ml. every 12 hours PRN;

- Norco (a narcotic pain reliever that combines hydrocodone with acetaminophen), [2] 10/325 mg., by mouth, every 8 hours PRN; and

- Lexapro (an antidepressant), 20 mg., by mouth, daily at bedtime.

CMS Ex. 23 at 75; P. Ex. 6 at 2 (Hutchens Decl. ¶ 5).[3]

There seems no dispute that R1 was a deeply troubled young woman whose relatively short stay at the facility was characterized by her heavy medications, repeated falls, and frequent hospitalizations.

On August 12, 2010, three weeks after her admission to the facility, R1 was hospitalized for a week because of worsening depression with suicidal ideation. CMS Ex. 22 at 1-4; CMS Ex. 23 at 2.[4]

In a September 1, 2010 report, the facility's consulting pharmacist, Melissa J. McGuire, PharmD, opined that R1's falls could be attributable to her multiple medications. Pharmacist McGuire also noted that the resident had "many behaviors and drug seeking tendencies." She recommended that R1's physicians, Dr. Shah and Dr. Lozono, evaluate ten listed medications – Wellbutrin, Risperdal, Klonopin, Geodon, Cyclobenzaprine, Benadryl, Norco, Ativan, Trazodone, and Lexapro – "as possibly causing or contributing to falls." If the therapy were to continue, she recommended that the prescribers document an assessment of risk versus benefit "indicating that the medication is not believed to be contributing to falls" and that the facility's interdisciplinary team "ensure ongoing monitoring for effectiveness and potential adverse consequences" of the drugs. CMS Ex. 23 at 166.

Petitioner has come forward with no evidence to suggest that either the prescribers or facility staff responded to the pharmacist's report. The sections of that report calling for a response are left blank. CMS Ex. 23 at 166. Petitioner's witnesses do not mention it either. P. Ex. 4 (Jude Decl.); P. Ex. 5 (Neese Decl.); P. Ex. 6 (Hutchens Decl.); P. Ex. 7 (Kaufman Decl.).

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[2] Norco is also marketed under the brand names Lorcet, Lortab, Vicodin, Zydone, and others.

[3] I have not necessarily been able to discern from the record before me an articulation of the specific condition for which each of these drugs was prescribed. Sometimes a justification is written in; sometimes it is not. *See* CMS Ex. 23 at 47-120.

[4] The resident herself reported the problem, surrendering her razors so that she would not be able to cut herself. CMS Ex. 23 at 125-26.

The falls continued. *See* CMS Ex. 23 at 26, 28, 29, 31.

R1 was hospitalized again on October 3, 2010, complaining of abdominal pain. In a bizarre episode, physicians diagnosed appendicitis, but, while performing the surgery, her physician discovered that her appendix had already been removed. CMS Ex. 22 at 5-6; CMS Ex. 23 at 2. She returned to the facility, and, in response to her ongoing complaints of pain, staff continued administering PRN Norco. *See* CMS Ex. 23 at 24, 27, 28.[5] Occasionally, staff delayed or declined her requests for Norco because she had exceeded the prescribed maximum of six tablets per day. CMS Ex. 23 at 20, 22.

In a report dated November 3, 2010, Consultant Pharmacist McGuire expressed particular concerns about the dosages of two prescribed drugs, Clonazepam (Klonopin) and Lorazepam (Ativan). R1's prescriptions called for 2 mg. Klonopin four times daily (or 8 mg. per day) as well as 1 mg. Ativan every four hours as needed (or up to 6 mg. per day). Pharmacist McGuire pointed out that the recommended maximum daily dose thresholds for these medications were 1.5 mg. for Klonopin and 2 mg. for Ativan. The pharmacist again asked that the prescribers evaluate continued use of the medications. She recommended that they document a risk versus benefit analysis, indicating that the medications continue to be valid therapeutic interventions. She again recommended that the facility's interdisciplinary team "ensure both ongoing monitoring for potential adverse consequences" and that it implement and monitor resident-specific non-pharmacologic interventions. CMS Ex. 23 at 165.

In a brief note, Dr. Lozono declined the recommendation, writing that the patient "continues to display out of control behaviors which may require PRN meds." CMS Ex. 23 at 165. According to the facility's director of nursing (DON), Jodi Foster Jude, R.N., Dr. Lozano rejected the pharmacist's recommendations, after she told him that R1's medications had curbed the resident's out-of-control behaviors. P. Ex. 4 at 2 (Jude Decl. ¶ 9). Neither the physician nor anyone from the facility responded to the pharmacist's recommendations that they ensure ongoing monitoring for potential adverse consequences and that they consider non-pharmacologic interventions.

[5] Throughout R1's medical record, staff document the resident's "drug-seeking" behavior as they give her the drugs that she requests. CMS Ex. 23 at 8, 27. Also striking are the times that staff administered Norco, documenting on the pain medication monitoring sheets that R1's pain was "severe" or "excruciating," even though the corresponding nurses' notes do not suggest anything near that level of pain, and, in one significant instance, describe her as "in no apparent distress." *Compare, e.g.*, P. Ex. 23 at 88 (noting excruciating pain at 7:00 a.m. and 1:00 p.m.) *with* CMS Ex. 23 at 16 (noting "up to request [receive] PRN meds. Conversing [with] staff. In no apparent distress . . . sleeping soundly for most of shift").

R1 was last hospitalized on November 16, 2010, with complaints of chest pain. CMS Ex. 22 at 8-69; CMS Ex. 23 at 17, 19. Cardiac and neurological testing were normal. CMS Ex. 22 at 42-44, 51, 52, 58, 60, 62, 63. Her hospital physician, James D. Wright, M.D., opined that her problems more likely related to "chronic pain, opioid dependence, and her underlying psychiatric problems, which no doubt include an element of post-traumatic stress disorder." He told R1 that her complaints of pain were "at least in part psychologically based and that the more pain medicine she takes, the more habituated her body becomes." CMS Ex. 22 at 51-52.

Nevertheless, for reasons that have not been explained, Dr. Wright prescribed a Fentanyl patch in addition to the PRN Norco, R1's already-prescribed narcotic pain reliever. CMS Ex. 22 at 33, 52. Fentanyl (Duragesic) is an opioid analgesic. It is a very powerful drug, at least 50 to 100 times as potent as morphine. CMS Ex. 29 at 11; CMS Ex. 30 at 1; *but see* CMS Ex. 24 at 9 (noting that the coroner's office reports it to be 80 to 200 times as potent as morphine). Those wearing the patches must be monitored closely, particularly "within the initial 24-72 hours when serum concentrations from the initial patch will peak." CMS Ex. 30 at 2.

In an order dated November 18, Dr. Wright also renewed the order for Norco PRN (as needed), but specified that *no more than 6 Norco tablets* could be administered per 24-hour period. CMS Ex. 22 at 33, 52.

No one at the facility questioned these prescriptions.

R1 returned to the facility at about 11:00 p.m. on November 18. Her respirations were "easy and unlabored"; she showed no signs of distress. CMS Ex. 23 at 5, 16. Staff began to fill out a 3-day assessment tool, with each shift recording her vital signs and other information. According to the form, the first shift reported her blood pressure (BP) at 136/71; pulse (P) at 90; and respirations (R) at 20. CMS Ex. 23 at 5.

For the next shift (6:00 a.m. to 2:00 p.m. on November 19), her vitals were: BP 120/73; P 114; and R 20. CMS Ex. 23 at 7.[6] During that shift, however, she showed signs consistent with the drug manufacturer's warnings of adverse consequences. She refused breakfast. CMS Ex. 23 at 16. At 7:00 a.m., according to a monitoring form, she complained of nausea and vomiting (recorded on the form as N/V). Staff administered Zofran. CMS Ex. 23 at 93. At 9:25 a.m., according to the nurses' notes, R1 said that she

[6] Citing CMS Ex. 23 at 7 and 8, Petitioner asserts that these and the third shift vital signs were taken at 1:30 p.m. and 9:30 p.m., respectively. P. Br. at 6. I am willing to accept the assertion, which, in any event, I do not find material. Nevertheless, after carefully reviewing the pages relied upon, I found no mention of the times the vitals were taken beyond a general reference to the hours of each shift.

was tired and complained of pain. Staff administered PRN Norco. R1 returned to bed, and slept "soundly for most of [the] shift," waking solely to request and receive PRN meds. CMS Ex. 23 at 16.

The third shift following her admission (2:00 p.m. to 10:00 p.m. on November 19) recorded her vital signs as: BP 142/84; P 88; R 20. CMS Ex. 23 at 8. During that shift (at 5:15 p.m.), she again complained of nausea and vomiting, and staff gave her Zofran. CMS Ex. 23 at 93. According to a late entry in the nurses' notes (written on the day of R1's death), during this shift, R1 requested and received her PRN medications. She spent most of the shift "resting in bed" but emerged when medications were passed. R1 told staff that she was "groggy" because the hospital put her on scheduled Geodon and Dilaudid, and she wanted to "sleep it off." CMS Ex. 23 at 16. Staff did not contact her physician, and they continued to administer her regularly scheduled drugs. CMS Ex. 23 at 87-88, 90, 92-95.

On the fourth shift following her readmission (10 p.m. to 6:00 a.m. on November 19-20), R1's vital signs were disturbing: BP was low at 100/58 (normal range for a healthy adult is 120/80); P was high at 128 (normal is 60-80), R 18. CMS Ex. 23 at 9; CMS Ex. 37.[7] At 1:15 a.m. during that shift, R1 was again complaining of nausea and vomiting, and staff again administered Zofran. CMS Ex. 23 at 93. She must also have been complaining of pain because staff administered an additional PRN dose of Norco, which, both parties agree, was her eighth dose in 18 hours, and, with this dosage, the facility exceeded the dosage limits Dr. Wright had included in his November 18 order – no more than 6 tablets per 24-hour period. CMS Ex. 23 at 88, 95; CMS Br. at 22; P. Br. at 7.

According to a nurse's note, at 7:00 a.m., R1 was still sleeping. Staff apparently woke her up, but "after waking up [R1] noted to be groggy so I held 8 AM meds." Staff did not take the resident's vital signs. CMS Ex. 23 at 17. A nurse aide later wrote that R1 told her that she did not want to eat breakfast. CMS Ex. 20 at 7. Someone else, whose position is not identified, wrote that she observed R1 "in bed snoring lightly" some time after 10:50 a.m. CMS Ex. 20 at 5. A housekeeper wrote that she observed the resident sleeping at about 11:00 a.m. CMS Ex. 20 at 7.

When a nurse went to her room at 12:15 p.m., R1 did not respond and had no pulse. Staff called 911 and attempted CPR, but R1 was pronounced dead. CMS Ex. 23 at 17.

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[7] According to Petitioner, staff took R1's vital signs at 5:30 a.m. P. Br. at 7. Again, the authority cited indicates only that the signs were taken between 10 p.m. and 6:00 a.m. It does not specify a time. CMS Ex. 23 at 9. As noted above, the exact timing is not material.

Following an autopsy, the coroner concluded that R1 died of combined drug intoxication. CMS Ex. 24. Among other findings, her Fentanyl blood level was 4.4 ng/ML (nanograms per milliliter). The coroner also found that R1's level of hydroxybupropion, to which Bupropion (Wellbutrin) metabolizes, was 420 ng/ML, just under a level (446) known to cause a delayed death due to overdose. CMS Ex. 24 at 6, 9.

A. CMS is entitled to summary judgment that the facility was not in substantial compliance with 42 C.F.R. §§ 483.25 and 483.25(l)(1) because the undisputed evidence establishes that: 1) in contravention of her physician's order, facility staff administered to R1 an excessive dose of Norco, a powerful narcotic pain medication; and 2) the facility did not adequately justify administering to that resident questionable drug combinations and dosages [8]

Program requirements. Under the statute and the "quality of care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act § 1819(b); 42 C.F.R. § 483.25. To that end, each resident's drug regimen must be free from unnecessary drugs. Unnecessary drugs are defined as any one or combination of the following: drugs used in excessive doses (including duplicate drug therapy); drugs used for an excessive duration; drugs that are not adequately monitored; drugs used without adequate indications for their use; and drugs whose adverse consequences indicate that they should be reduced or discontinued. 42 C.F.R. § 483.25(l)(1).

Application of law to the undisputed facts: staff administered an excessive dose of Norco. Here, everyone agrees that, between 7:00 a.m. on November 19 and 1:15 a.m. on November 20 (just over 18 hours), staff administered to R1 eight tablets of Norco, even though her physician's order explicitly limited the dosage to no more than six tablets per 24-hour period. CMS Ex. 22 at 33, 52; CMS Ex. 23 at 88, 95; CMS Br. at 22; P. Br. at 7, 17.

Staff thus administered an excessive dose of Norco, in contravention of the physician's order. No one disputes that the standard of care mandates that staff follow physician's orders.

Nevertheless, citing the testimony of its own forensic pathologist, Michael W. Kaufman, M.D., Petitioner argues that R1's death was caused by "respiratory depression caused by

[8] My findings of fact/conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

excessive presence of Fentanyl" and that "the administration of Norco was not a cause or contribute to cause the resident's death." P. Br. at 7-8 (citing P. Ex. 7 at 2 (Kaufman Decl. ¶¶ 5, 7)). Dr. Kaufman also opines that "the administration of the two tablets of Norco at 1:15 AM on November 20, 2010 did not present a threat of actual harm to the resident, even in light of the other drugs [that] had been prescribed for her." P. Ex. 7 at 3 (Kaufman Decl. ¶ 8). For purposes of summary judgment, I accept Dr. Kaufman's opinion that Fentanyl, not excessive Norco, caused R1's death and that the excessive Norco caused no actual harm.

The standard for substantial noncompliance, however, is not whether the excessive dose of Norco actually killed the resident, nor even whether it caused her actual harm. The standard is whether the deficiency presented the potential for more than minimal harm. Whether the deficiency meets this standard is a legal conclusion, not a finding of fact, so, for summary judgment purposes, I need not defer to Dr. Kaufman's opinion as to whether that standard is met. I note, nevertheless, that, in his carefully-worded declaration, Dr. Kaufman stops short of claiming that giving an already-heavily-sedated woman significantly more narcotics (a third more within a twenty-four hour period) than authorized by her physician poses no potential for more than minimal harm.

Moreover, no one claims that staff can safely disregard medication orders, and the deficiency here is broader than an instance of their administering narcotics that were not authorized by a physician's order. When it came to drugs, R1 was especially vulnerable. She was taking a lot of drugs in high doses; the facility's consulting pharmacist had twice questioned whether the drug regimen was justified; a powerful narcotic (Fentanyl) had just been added to her already-extensive drug regimen; the Norco itself contains hydrocodone, which is more toxic than codeine. CMS Ex. 24 at 9. Facility staff therefore had a heightened duty to monitor carefully the drugs R1 was taking, particularly the PRN narcotics, and to ensure that she was not administered anything more than had been ordered. The staff's failure to follow the physician's order when it really mattered raises questions about the procedures the facility had in place to ensure that staff did not exceed physician orders for narcotics.

In defending the charge that it over-medicated R1, Petitioner makes much of its obligation to follow physicians' orders. Yet, the facility shows no apparent concern for its staff's disregard of the physician's order in this critical instance. Petitioner's witnesses are quick to opine that the facility complied with the regulations protecting residents from unnecessary drugs, but, in doing so, they fail even to acknowledge this error, much less to explain why it occurred and why I should not conclude that the deficiency posed the potential for more than minimal harm. Petitioner submits no statements from the nurse who administered the drug. DON Jude says nothing about it. P. Ex. 4. Nurse Consultant Barbara Hutchens, R.N., talks about the staff administering the Norco at 1:15 a.m. (during the 10 p.m. to 6 a.m. shift on November 19-20), but she disregards the fact that the drug was administered without a valid physician order. She

says "in my professional opinion, it was appropriate for the staff to administer the Norco in response to the resident's complaints of pain, as ordered by her physician" and concludes that "[t]he administration of the resident's medications on November 19, 2010 did not violate the standard of care or any federal regulations." P. Ex. 6 at 6 (Hutchens Decl. ¶ 11); *see* P. Ex. 6 at 3 (Hutchens Decl. ¶ 5).[9]

I reject these conclusions as unreasonable. Administering a narcotic in contravention of a valid physician order is neither "appropriate" nor within the standard of care, and it violates the federal regulations governing quality of care (42 C.F.R. § 483.25) and protecting residents from unnecessary drugs (42 C.F.R. § 483.25(l).

Also troublesome, Nurse Consultant Hutchens recognizes that staff administered the drug because R1 requested it, but she describes the resident as "conversing with staff" and "in no apparent distress" at the time, which should have raised additional significant questions as to why the drug was given. P. Ex. 6 at 3 (Hutchens Decl. ¶ 5). Yet, it seems that no one at the facility asked this question.

Thus, because staff administered excessive Norco to R1, in contravention of her physician's order, the facility violated 42 C.F.R. §§ 483.25 and 483.25(l).

Application of law to the undisputed facts: the facility did not justify questionable combinations and dosages of drugs. On September 1, Consultant Pharmacist McGuire questioned ten of R1's medications and recommended that the prescribers and facility staff reassess their benefits versus risks and develop a plan for monitoring their effectiveness and adverse consequences. CMS Ex. 23 at 166. Petitioner has not disputed any of this and cites no evidence suggesting that facility staff responded to the pharmacist's legitimate concerns. Indeed, Petitioner's brief and its witness declarations are conspicuously silent regarding the pharmacist's September 1 report.

In her second report, Consultant Pharmacist McGuire raised more specific concerns. She pointed out that the prescribed dosages of two drugs, Clonazepam (Klonopin) and Lorazepam (Ativan), far exceeded the manufacturers' recommendations. The manufacturer recommended no more than 1.5 mg. per day of Klonopin; R1 took 8 mg. per day. The manufacturer recommended no more than 2 mg. per day of Ativan; R1 was prescribed up to 6 mg. per day. CMS Ex. 23 at 165; CMS Ex. 28 at 45-46. R1 was thus regularly taking more than five times the maximum recommended dosage of Klonopin plus up to triple the maximum dosage of Ativan. CMS Ex. 23 at 165.

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[9] I am assuming that Nurse Consultant Hutchens refers to all of the Norco administered on the 10 p.m. to 6 a.m. shift of November 19-20, which, as discussed, makes her conclusion unreasonable. However, if she is limiting her opinion to the drugs given on November 19, then she apparently does not claim that staff acted appropriately in administering the eighth dose.

Further, as noted above, "unnecessary drugs" include duplicate drug therapy. 42 C.F.R. § 483.25(l)(1). In its State Operations Manual (SOM), CMS defines "duplicate therapy" as "multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking." CMS Ex. 28 at 4.

> Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects . . . . Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences.

CMS Ex. 28 at 20.

CMS points out that Lorazepam (Ativan) and Clonazepam (Klonopin) fall into the same category of medications – they are both anxiolytics. CMS Ex. 28 at 45; CMS Ex. 36 at 7 (Kaplow Decl. ¶ 35) (stating that Lorazepam and Clonazepam "are in the exact same family of drugs").[10] Combining the two drugs is therefore inappropriate, unless the facility shows that "current clinical standards" and "documented clinical rationale" justify the practice. Petitioner offers no evidence that current clinical standards of practice "confirm the benefits" of combining these two drugs. Nor has Petitioner produced documentation to clarify the rationale for or benefits of the therapy. I see no documentation of its approach to monitoring for benefits/adverse consequences.

Petitioner's response to this is that Dr. Lozano "expressly confirmed that he wanted his orders followed." P. Br. at 17. A physician's order, however, is insufficient to satisfy the requirements of the regulation. Responding to comments, the drafters of the regulation explained that an "unnecessary drug" is "reserved for drug therapy circumstances" that CMS guidelines establish "are a potential threat to the resident's health and safety, and for which the facility is unable to justify why using a drug under such circumstances is in the best interest of the resident." The facility "can certainly rely on physician justification of the risk-benefit of the drug use," but *it cannot simply claim that "the doctor ordered it*." Requiring only a physician's order to justify a questionable drug "would render the regulation, and the statutory underpinnings for it, meaningless." 56 *Fed. Reg.* 48,826, 48,851-52 (Sept. 26, 1991) (emphasis added).

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[10] This is not the only instance of duplicate therapy. R1 had prescriptions for Tylenol (acetaminophen) and Norco, which is hydrocodone with acetaminophen. The SOM specifically cites this as a problematic example of duplicate therapy, noting that it can increase the risk of acetaminophen toxicity. CMS Ex. 28 at 20. CMS did not cite this particular combination as a problem here, so I do not consider the question.

Thus, without regard to the excess dose of Norco, undisputed evidence establishes that the facility administered to R1 unnecessary drugs within the meaning of 42 C.F.R. § 483.25(l) and was therefore not in substantial compliance with program requirements.

B. CMS is also entitled to summary judgment because the undisputed evidence establishes that the facility staff: 1) did not adequately monitor R1 for potential adverse consequences from her drug regimen, in contravention of 42 C.F.R. §§ 483.25 and 483.25(l); and 2) in contravention of 42 C.F.R. § 483.10(b)(11), did not immediately consult the resident's physician when she exhibited symptoms of a drug overdose.

Program requirements. As noted above, drugs that are not adequately monitored are considered unnecessary. 42 C.F.R. § 483.25(l)(1). Referring specifically to opioids (like Norco and Fentanyl), the SOM emphasizes the importance of monitoring for adverse consequences:

> Adverse consequences may be especially problematic when the resident is receiving other medications with significant effects on the cardiovascular and central nervous systems. Therefore, careful titration of dosages based on monitoring/evaluating the effectiveness of the medication and the occurrence of adverse consequences is necessary. The clinical record should reflect the ongoing communication between the prescriber and the staff . . . necessary for the optimal and judicious use of pain medications.

CMS Ex. 27 at 22.

In addition, to protect and promote the rights of each resident, the facility must *immediately* inform the resident, consult the resident's physician, and (if known) notify the resident's legal representative or interested family member when there is: a significant change in the resident's physical, mental, or psychosocial status (*i.e.*, a deterioration in health, mental or psychosocial status in either life-threatening conditions or clinical complications); or a need to alter treatment significantly (*i.e.*, a need to discontinue an existing form of treatment due to adverse consequences or to commence a new form of treatment). 42 C.F.R. § 483.10(b)(11) (emphasis added).

"Significant" means "all cases, whether or not there is a medical emergency." 56 *Fed. Reg.* at 48,833. "Immediately" means "as soon as the change . . . is detected, without any intervening interval of time." *Magnolia Estates Skilled Care*, DAB No. 2228 at 8 (2009); *The Laurels at Forest Glen*, DAB No. 2182 at 13 (2008).

Application of law to the undisputed facts – inadequate monitoring and failure to consult physician about a significant change. The dangers associated with Fentanyl are well-documented. The drug's manufacturer, the Food and Drug Administration (FDA), and others provide stern warnings to those who administer the drug and those who take it. According to its manufacturer:

> **Fentanyl is a very strong opioid narcotic pain medicine that can cause serious and life-threatening breathing problems. Serious and life-threatening breathing problems can happen because of an overdose or if the dose you are using is too high for you.[11] Call your doctor right away or get emergency medical help if you:**
>
> - have trouble breathing, or have slow or shallow breathing
> - have a slow heartbeat
> - have severe sleepiness
> - have cold, clammy skin
> - feel faint, dizzy, confused, or cannot think, walk, or talk normally
> - have a seizure
> - have hallucinations.

CMS Ex. 30 at 8 (emphasis in original).

The FDA issued its own warnings in the form of a 2007 public health advisory that says:

> Healthcare professionals who prescribe and patients who use the fentanyl patch should be aware of the signs of fentanyl overdose including the following: trouble breathing or slow or shallow breathing; slow heartbeat; severe sleepiness; cold, clammy skin; trouble walking or talking; or feeling faint, dizzy or confused. If these signs occur, patients or their caregivers should get medical attention right away.

CMS Ex. 31 at 4; *accord* CMS Ex. 28 at 29 (in which the SOM notes that adverse consequences include nausea, vomiting, sedation, lethargy, weakness, confusion, and unintended respiratory depression); CMS Ex. 29 at 8 (per 2010-2011 Drug Information

[11] According to Petitioner, the facility "*could not* have known of the patch release medication at a rate resulting in overdoses." P. Br. at 9 (quoting IDR findings) (emphasis in original). I am puzzled by this statement. While facility staff may not have understood the precise mechanism by which the patch delivered the drug, the drug's manufacturer warns – in bold letters – of the potential for overdose. For this reason, I cannot understand why facility staff "could not have known" of the danger and monitored the resident accordingly.

Handbook, drowsiness, fatigue, sedation, nausea/vomiting, and hyper-hypotension (low blood pressure) are adverse reactions to Fentanyl).

A 2009 article from the journal Nursing warns that even opioid-tolerant patients "can experience serious or life-threatening opiod-induced hypoventilation when starting therapy with a fentanyl patch" and advises "[c]losely monitor your patient to avoid oversedation." CMS Ex. 33 at 1. The article lists signs of an overdose and instructs healthcare providers to "intervene immediately" if the patient develops respiratory distress, extreme sleepiness or sedation, or other symptoms listed. CMS Ex. 33 at 2.

In light of these warnings, the facility should have had in place a plan to assure the close level of monitoring appropriate for a highly-medicated resident who had just been given a Fentanyl patch. Instead, by its own admission, it treated R1 as it would any resident, taking her blood pressure and vital signs just once per shift. According to Nurse Consultant Hutchens, "staff should be monitoring the resident and taking vital signs once a shift" regardless of the resident's medication orders. P. Ex. 6 at 4 (Hutchens Decl. ¶ 8). Certainly, a routine blood pressure check every eight hours does not constitute the careful monitoring required for a patient taking Fentanyl.

Even if the facility could be excused for initially treating R1 as it would any other resident, it should have ratcheted up the monitoring when she began to exhibit symptoms of Fentanyl overdose, and, as CMS argues, it should have consulted her physician immediately when she first exhibited such symptoms: nausea and vomiting; extreme sleepiness; and a drop in blood pressure accompanied by an elevated pulse.

By all accounts, when R1 returned to facility on the night of November 18, she was fine; her vital signs were normal, and she showed no signs of distress. CMS Ex. 23 at 5, 16. By November 19, however, she began to show some of the symptoms associated with a drug overdose. That morning, she complained of nausea and vomiting. She refused breakfast. CMS Ex. 23 at 16, 93. By the afternoon/evening shift, she again complained of nausea/vomiting, and said that she felt groggy and wanted to "sleep it off." She attributed her grogginess to medications (Dilaudid and Geodon) she took while hospitalized, and staff apparently never questioned her opinion. CMS Ex. 23 at 16.

By the morning of November 20, her symptoms were more pronounced. Her severe sleepiness continued (even though she had been sleeping or resting most of the time since she returned from the hospital). CMS Ex. 23 at 16-17. In fact, she was so groggy that the nurse withheld her 8:00 a.m. medications. Her blood pressure dropped from 142/84 to 100/58 and her pulse rose from 88 to 128. CMS Ex. 23 at 8, 9, 17.

Staff did not contact her physician; they did not increase their level of monitoring; they did not even take her vital signs again.

Petitioner excuses its staff's actions (or inactions) by arguing that R1's symptoms were few and did not suggest life threatening conditions. According to Petitioner, R1's symptoms were not so significant that they "should have alerted a reasonably prudent nurse that R1 was at risk for a fatal overdose of Fentanyl." P. Br. at 12. But "significant" does not mean "life-threatening"; it does not even require a medical emergency. Drafters of the regulation emphasized that, "in all cases, whether or not there is a medical emergency," the facility must immediately consult the attending physician. 56 *Fed. Reg.* at 48,833; *The Laurels at Forest Glen,* DAB No. 2182 at 11-13.

Next, Petitioner argues that, because R1 had exhibited virtually all of these symptoms before, they could not be considered significant. Under this theory, staff did not have to consult the physician about a drop in her blood pressure, because her blood pressure was erratic; staff did not have to consult the physician about her nausea and vomiting, because she had been nauseous and vomiting before; staff did not have to consult the physician about her sleepiness, because she regularly slept until noon, which DON Jude characterizes as a "lifestyle choice." P. Ex. 4 at 2 (Jude Decl. ¶ 7).

Setting aside the questionable characterization of this heavily-sedated resident's inclination to sleep as a "life style choice," Petitioner's theory means that the facility would virtually never be compelled to consult the resident's physician when she exhibited symptoms of a drug overdose, because, at one time or another, she exhibited virtually all of these symptoms (which is not surprising, considering how heavily medicated she was).

Vital signs. In any event, Petitioner's argument fails because the undisputed evidence leads to only one reasonable conclusion – in the roughly 36 hours following her return to the facility, R1's condition changed significantly. I accept that her blood pressure was erratic and occasionally dipped as low as, or lower than, it was on the morning of November 20. But her pulse had never been as high as 128, and the combined low blood pressure/elevated pulse was unusual for her. *See* Ex. P. Ex. 4 at 3-4 (Jude Decl. ¶ 11) (showing only one instance of combined low blood pressure and elevated pulse, which, at 101, was not nearly as high as the 128 recorded on the morning of November 20). In testimony that Petitioner does not challenge, Surveyor Cheryl D. Strother, R.N., explains

> When the blood pressure suddenly drops, the heart will speed up in an attempt to raise the blood pressure. If the blood pressure does not return to normal range, then the whole system shuts down. When this happens, the blood pressure, heart rate and respiratory rate all continue to drop until the person dies.

CMS Ex. 34 at 3 (Strother Decl. ¶ 14). Staff should thus have consulted R1's physician immediately when she exhibited low blood pressure/high pulse. Even if they did not recognize the significance of these changes (which they should have), their subsequent failure to monitor R1's vital signs is simply inexplicable. Had they done so, they might have recognized that her blood pressure, heart rate, and respiratory rate were dropping, giving them the opportunity to intervene before it was too late.[12]

Nausea/vomiting. Facility staff say nothing about R1's symptoms of nausea/vomiting on or before November 19-20. *See* P. Ex. 4 (Jude Decl.); P. Ex. 5 (Neese Decl.). Without any citation to the record, Petitioner claims that R1 "demonstrated . . . symptoms [of nausea] long before the Fentanyl patch was administered." P. Br. at 17-18. Nurse Consultant Hutchens, who has no personal knowledge of R1's symptoms, is the only facility witness who addresses the question. She declares:

> The presence of the complaint of nausea was not related to the administration of Fentanyl. The same complaint of nausea was present in this resident before she was ever given Fentanyl, and there was no change in this complaint after the Fentanyl patch was administered.

P. Ex. 6 at 4 (Hutchens' Decl. ¶ 8).

Nurse Consultant Hutchens' logic is flawed. Just because R1 had previously experienced nausea, for reasons unrelated to Fentanyl, does not mean that her complaints of nausea and vomiting on November 19 and 20 were therefore unrelated to the Fentanyl.[13]

Moreover, Nurse Consultant Hutchens' inference that R1 was consistently nauseous – so that her complaints of November 19 and 20 did not represent a change – is contrary to the evidence and therefore not reasonable. In fact, the record shows that R1's prior complaints of nausea were relatively few, and each one led to a significant medical intervention.

R1's complaints of nausea and vomiting were first documented on October 3, when she was hospitalized, complaining of "significant amounts of nausea and vomiting." CMS Ex. 22 at 5; CMS Ex. 23 at 29. Following her return to the facility, however, she had no such complaints until October 25. At that time, she complained of nausea and difficulty

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[12] The drug Naloxone can be administered as an antidote to Fentanyl overdose. CMS Ex. 32 at 3.

[13] The fallacy of her reasoning is illustrated by the following example: Mary ate tainted food; Mary has a stomach ache; Mary has had stomach aches without eating tainted food; therefore, tainted food did not cause Mary's stomach ache.

urinating, which resulted in her being catheterized. CMS Ex. 23 at 22. She had the same problems on October 30 and was sent to the emergency room, where she was again catheterized. CMS Ex. 23 at 23.[14] I found no evidence that she experienced any other symptoms of nausea/vomiting until November 16. CMS Ex. 23 at 18, 20, 21.[15] She vomited once immediately prior to her hospitalization that day; although, by the time of her hospital admission, she no longer complained of nausea/vomiting. CMS Ex. 22 at 39-41; CMS Ex. 23 at 17. When she returned to the facility on the night of November 18, she had no such symptoms. CMS Ex. 23 at 6, 16.

Only one reasonable inference can be drawn from these undisputed facts – when R1 exhibited symptoms of nausea/vomiting, she had a significant underlying problem that required immediate medical attention. Thus, even if staff did not recognize her nausea as a symptom of Fentanyl toxicity, they should have recognized it as evidence of a need to alter her treatment and should have consulted her physician immediately.

Severe sleepiness. I recognize that R1 generally had a sleepy affect and that she regularly slept late.[16] But her behavior on November 20 went far beyond anything she had displayed before. She had been sleeping/resting virtually non-stop since she returned from the hospital. Nursing notes describe her as sleeping through most of the 6:00 a.m. to 2:00 p.m. shift on November 19. She spent the entire 2:00 p.m. to 10:00 p.m. shift "resting in bed." She was still sleeping at 7:00 a.m. the following morning, having only gotten up at 1:15 a.m. to request medication, and she remained asleep until the time of her death, between 11:00 a.m. and 12:15 p.m. CMS Ex. 23 at 16-17; CMS Ex. 20 at 7.

The responsible nurse was so concerned that she unilaterally altered the resident's treatment, withholding her 8:00 a.m. medications. She drafted a physician's order to justify her withholding the medications but did not call the physician for approval of that order. CMS Ex. 23 at 46. According to Nurse Consultant Hutchens, the nurse withheld medications because the resident was sleeping at the time of the medication pass. P. Ex. 6 at 5 (Hutchens Decl. ¶ 9). Based on what the nurse wrote, this is not a reasonable inference. The nurse wrote, "[a]fter waking up [resident] she was noted to be groggy so I

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[14] Severe stomach/abdominal pain and difficulty urinating are "unlikely but serious side effects" of Norco. www.nlm.nih.gov/medlineplus/druginfo/meds; www.rxlist.com/narco-drug.htm.

[15] Prior to November 19, no monitoring sheets indicate that PRN Zofran was administered to treat nausea. *See* CMS Ex. 23 at 93, 111.

[16] DON Jude and the facility's behavioral health director, Licensed Practical Nurse Steven Neese, concede that R1's drug regimen left her sleepy most of the time but say that, because they considered the heavy sedation necessary to control her behavior, they told her physician they did not want it changed, and her physician complied. P. Ex. 4 at 2 (Jude Decl. ¶ 9); P. Ex. 5 at 2 (Neese Decl. ¶ 7).

held 8 AM meds." CMS Ex. 23 at 17. Even though R1 usually had a sleepy affect, no evidence suggests that staff had ever before considered the symptom of such concern that they withheld ordered medications. In fact, notwithstanding her sleepiness, R1 regularly got out of bed to request her medications.

No monitoring. Finally, the undisputed evidence establishes that facility staff were not adequately monitoring R1 on the morning of November 20. I accept, for summary judgment purposes, that two or three staff members happened to observe R1 while they engaged in other duties. Someone, who came into the room to fetch her roommate, noticed R1 sleeping; a housekeeper, engaged in other duties, also happened to see her. CMS Ex. 20 at 5, 7. But such casual observations do not constitute the careful monitoring called for when a resident has been administered large doses of powerful drugs, particularly where that resident has been exhibiting symptoms of drug toxicity.

Thus, the undisputed facts establish that, from November 19 until the time of her death on November 20, R1 exhibited alarming symptoms consistent with a Fentanyl overdose. Because facility staff failed to monitor her deteriorating condition and failed to consult her physician about her symptoms, the facility was not in substantial compliance with 42 C.F.R. §§ 483.25, 483.25(l), and 483.10(b)(11).

C. The penalty imposed is not unreasonably high.

To determine whether a CMP is reasonable, I apply the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the section 488.438(f) factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Ctr.*, DAB No. 1848 at 21 (2002); *Cmty. Nursing Home*, DAB No. 1807 at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800 at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1638, at 8 (1999). Here, the penalty imposed – $300 per day – is at the low end of the penalty range ($50-$3,000) for per-day CMPs where the facility's deficiencies do not pose immediate jeopardy to resident health and safety. 42 C.F.R. §§ 488.408(d); 488.438(a)(1).

Petitioner has a dismal compliance history. By its own admission, it is a "special focus facility," which means that, because of its significant history of noncompliance, it is subject to more careful monitoring. *See Jennifer Matthews Nursing & Rehab. Ctr.*, CR1717 at 30 (2007), *aff'd*, DAB No. 2192 (2008). Its history of noncompliance includes repeated failures to comply with the quality-of-care regulation (42 C.F.R. § 483.25 – Tag F309). In May 2005, November 2007, and June 2010, its deficiencies under that tag were also cited at scope and severity level G, which means that the deficiency caused actual harm. In August 2005 and March 2007, the facility's quality-of-care deficiencies posed immediate jeopardy to resident health and safety. CMS Ex. 3. The facility's history alone justifies a significant penalty.

Petitioner does not claim that its financial condition affects its ability to pay the $3,900 CMP.

I need not even consider the remaining factors to sustain this astonishingly low penalty. But I consider the deficiencies very serious. Any one of them would more than justify the penalty imposed. This heavily-sedated woman exhibited symptoms of drug toxicity, including falling blood pressure, yet staff did not even make a follow-up blood pressure check or otherwise monitor her condition. This failure evidences a significant disregard for her care, comfort and safety, for which the facility is culpable.

D. CMS's scope and severity finding is not reviewable in this forum.

CMS cited deficiencies at scope and severity level G, which indicates actual harm. Petitioner challenges those scope and severity findings. According to Petitioner, "the scope and severity findings have an unusually adverse impact on the facility and its owners' ability to market the facility," because, based on those findings, the facility's designation as a "[s]pecial [f]ocus [f]acility" will likely continue. P. Br. at 2 n.2.

I recognize that scope and severity findings may cause unfavorable collateral consequences, but such considerations do not override the regulations by which I am bound. Those regulations limit my authority to review scope and severity.

An ALJ may review CMS's scope and severity findings, only if a successful challenge would affect the range of the CMP or if CMS has made a finding of substandard quality of care that results in the loss of approval of a facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14); 42 C.F.R. § 498.3(d)(10); *Cedar Lake Nursing Home*, DAB No. 2344 at 9; *Evergreen Commons*, DAB No. 2175 (2008); *Aase Haugen Homes*, DAB No. 2013 (2006). Here, the deficiencies were cited at a G level of scope and severity, rather than immediate jeopardy, which means that the per-day penalty is already in the lower range ($50 to $10,000). A successful challenge to scope and severity would therefore not affect the range of the CMP. 42 C.F.R. § 488.438(a)(2). The parties also seem to agree

that the facility has not lost approval of its nurse aide training program. CMS Br. at 4; P. Br. at 2-3 n.2. CMS's scope and severity determination is therefore not reviewable here.

IV. Conclusion

I grant CMS's motion for summary judgment, because the undisputed facts establish that the facility was not in substantial compliance with 42 C.F.R. §§ 483.25, 483.25(l), and 483.10(b)(11). I sustain the penalty imposed ($300 per day).

/s/
Carolyn Cozad Hughes
Administrative Law Judge